(4)

No. 09-116

Supreme Court, U.S.
FILED
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In the

Supreme Court of the United States

VALER V. SECAREA, JR.,
Plaintiff, Appellant and Petitioner

v.

REGENTS OF THE UNIVERSITY
OF CALIFORNIA,
KALYANAM SHIVKUMAR, M.D.,
DAVID CESARIO, M.D.,
CHARLES SWERDLOW, M.D.,
Defendants and Respondents

PETITION FOR WRIT OF CERTIORARI REPLY TO OPPOSITION BY RESPONDENT CHARLES SWERDLOW, M.D., AND APPENDIX C

After a Decision by the California Court of Appeal,
Fourth Appellate District, Division Three

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In Propria Persona

TABLE OF CONTENTS

I. Petition Redux: This Petition is mainly about medical experimentation. Reduced to its lowest common denominator, it is whether the Fourteenth Amendment to the U. S. Constitution protects unknowing patients from state-sponsored covert medical device studies whose consent requirements are governed by federal regulation -- or whether human subject researchers are "above the law," beyond the reach of the constitution's equal protection guarantees 1

II. Respondent Charles Swerdlow's accusation that this Petitioner improperly submitted documents to this Court is false! 3

III. Respondent Researcher, Charles Swerdlow, M.D., now admits to this Court that he experimented on patients without their knowledge or consent. But, to the California Supreme Court he claimed there was no experimentation 5

IV. After admitting to covert experimentation on unsuspecting patients, Respondent Charles Swerdlow, M.D., cannot now claim that his conduct was "within the standard of care" or claim that he was entitled to the summary judgment at issue in this petition 7

V. Dr. Swedlow claims that the issues in this Petition do not apply to him. However, even though he is apparently a "part-time" public employee, the issues apply to his conduct, in any event 9

VI. Contrary to Dr. Swerdlow's contention, Rule 10 provides that conscription by government and/ or its agents, of unknowing and helpless patients as objects of medical experimentation and student training, is one of the most compelling reasons of all for this Court to grant certiorari 10

VII. Respondent Charles Swerdlow, M.D., asserts that Nadine did not restrict her consent to specifically identified surgeons. But, this claim is shown to be entirely false by the documents now before this court 11

VIII. Researcher Charles Swerdlow, M.D. asks this Court to deny this Petition on the basis of a lack of conflict in the courts, all the while patients continue to be "kidnaped" from their hospital beds and subjected to covert medical experiments . 13

IX. Respondent Charles Swerdlow, M.D. claims that the loss of life to medical experimentation underlying this Petition is unlikely to recur, even though many continue to be subjected to covert experimentation 14

X. Conclusion: The only question posed by Researcher Charles Swerdlow's objections to this Petition is: how many more helpless and unsuspecting patients will die before this Court determines whether there is constitutional protection from this conduct? 15

APPENDIX C C-1

California Evidence Code
§§ 451, 452, 453, 454, 455, 459 ..... C-3

California Evidence Code § 451 ..... C-5
California Evidence Code § 452 ..... C-6
California Evidence Code § 453 ..... C-7
California Evidence Code § 454 ..... C-7
California Evidence Code § 455 ..... C-8
California Evidence Code § 459 ..... C-9

California Rules of Court Rule 8.252 ..... C-11
(a) Judicial notice C-13
(b) Findings on appeal C-13
(c) Evidence on appeal C-13

UCLA MEDICAL CENTER
CONSENT TO OPERATION
AND OTHER PROCEDURES C-15

AOB Excerpt re:
Proof of Medical Experimentation C-21

2. UCLA Defendants' Motion for Summary Judgment did not meet the initial burden of proof that all theories of liability raised had no merit and that there were no triable issues C-23

d. There is a triable issue as to whether the UCLA Respondents conducted medical experimentation upon Nadine, which required her informed consent C-23

TABLE OF AUTHORITIES

Federal Cases

Boyd v. United States,
116 U.S. 616 (1886) 11

Dennis v. Sparks,
449 U.S. 24, 27 (1980) 10

In Re Cincinatti Radiation Litigation,
874 F. Supp. 796 (S.D. Ohio 1995) 11

Slater v. Optical Radiation Corp.,
961 F.2d 1330, 1334 (7th Cir. 1992) 3

Spenceley v. M.D.Anderson Cancer Ctr.,
938 F. Supp. 398, 398 (S.D. Tex.1996) 7

U. S. Supreme Court Rules

Rule 14.1 (i) (vi) 4

California Cases

Bushling v. Fremont Medical Center
117Cal.App.4th 493 (2004) 8

Daum v. Spine Care Medical Group, Inc.,
52 Cal.App.4th 1285 [61 Cal.Rptr.2d 260](1997) . 13

Kelley v. Trunk
66 Cal. App.4th 519 (1998) C-23

California Rules of Court

Rule 8.252 (a) Judicial Notice 3, C-13

Rule 8.252 (b) Findings on Appeal C-13

Rule 8.252 (c) Evidence on Appeal C-13

California Statutes

Evidence Code § 451 ..... C-5

Evidence Code § 452 ..... C-6

Evidence Code § 453 ..... C-7

Evidence Code § 454 ..... C-7

Evidence Code § 455 ..... C-8

Evidence Code § 459 ..... C-9

I. Petition Redux: This Petition is mainly about medical experimentation. Reduced to its lowest common denominator, it is whether the Fourteenth Amendment to the U. S. Constitution protects unknowing patients from state-sponsored covert medical device studies whose consent requirements are governed by federal regulation -- or whether human subject researchers are "above the law," beyond the reach of the constitution's equal protection guarantees. [1]

This Petition is primarily about whether the Constitution affords protection from bodily invasion by state actors for the purpose of medical device experimentation, an enterprise that is governed almost entirely by federal statutes and regulation,[2] as alleged in the Complaint[3] or whether human subject researchers are beyond the reach of constitutional guarantees.

For example, a DHHS OHRP warning letter to the University of California ate San Francisco (UCSF)[4]

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[1] Condensed from page 1 of this Petitioner's Petition for Review to the California Supreme Court.

[2] Petition Appendix B-291 - B-301: "FDA regulations apply to 'everyone.'"); Appendix B-20 - B-40 (SAC §§44-84): describing protection of human subjects in medical device experimentation under the FDCA; Appendix A-99 (AOB extract at pp 33-35 "Regulations as a standard of care").

[3] "Complaint" refers to the Second Amended Complaint (SAC).

[4] Petition, p. 18; Appendix B-305: 13 January 2003 DHHS OHRP warning letter to Regis Kelly, Ph.D., Vice Chancellor for Research, UCSF,

describes experimentation on 6 patients, killing two. Apparently, no one was held accountable in these deaths. The only sanction was described at page 2:

> ... write to the four surviving subjects who received experimental treatment before the research was reviewed and approved by the IRB, and to the relatives of the two subjects who are now deceased, to inform them that they (or their relatives) were enrolled in a research study without consent and without IRB approval.

In addition if the researcher wished to "use data from these six subjects in any additional publications, he must request permission from surviving subjects or relatives." And the dead patients? So far as this Petitioner was able to ascertain, they were simply "discarded," like so much "laboratory waste," as if their consent to being subjected to experimentation was irrelevant -- and their lives had no value at all.

Respondent Researcher, Charles Swerdlow, contends that there are no federal issues to decide in this case .[5] But this contention is entirely without merit, because lack of informed consent may form the basis for a state claim involving federal medical device regulations, since such a claims are not preempted by

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http://www.hhs.gov/ohrp/detrm_letrs/YR03/jan03b.pdf.

[5] Charles Swerdlow, M.D., Opposition to Petition for Writ of Certiorari, p. 11-12 (hereinafter, "Opposition").

federal law. (*Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir. 1992)..

II. Respondent Charles Swerdlow's accusation that this Petitioner improperly submitted documents to this Court is false ![6]

There is no impropriety. As to the Request for Judicial Notice filed with the California Court of Appeals, California Rules of Court, Rule 8.252 (a), permits motions for judicial notice to a reviewing court.[7] The timeliness of this Petitioner-Appellant's motion, in light of recently discovered documents ,[8] as well as its adherence to California statutes and California Rules of Court, was fully explained .[9] Indeed, Dr. Swerdlow's assertion of impropriety to this Court is itself "improper," because, in California, reviewing courts have the same power as trial courts to take judicial notice,[10] as well as the power make findings and take evidence.[11]

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[6] Opposition, p. 12.

[7] This Volume, Appendix C-13: California Rules of Court, Rule 8.252, Judicial Notice on Appeal.

[8] Petition Appendix B-338 - B-342.

[9] Petition Appendix B-276 - B-280: "Introduction and Points and Authorities; Appendix C-3: Pertinent California Evidence Code sections and Appendix C-13: California Rules of Court, Rule 8.252, Judicial Notice on Appeal.

[10] Appendix C-9: California Evidence Code § 459.

[11] Appendix C-13: California Rules of Court, Rule 8.252.

Likewise, accusations of impropriety regarding the excerpts taken from Respondent, David Cesario, M.D., are equally false.[12]

Rule 14,[13] *Content of a Petition for a Writ of Certiorari*, at section 14.1(i)(vi): provides that a petition appendix may include "any other material the petitioner believes essential to understand the petition."

Dr. Cesario's admissions that he was a student in training at the time of Nadine's procedure,[14] that Nadine Secarea was subjected to a medical device experiment,[15] the experiment ultimately failed,[16] the experiment was not conducted according to the FDA regulations required of all device studies of the kind Nadine was subjected to,[17] the experiment was based on no scientific principle[18] and Dr. Swerdlow all but abandoned Nadine after the injury he caused began to take her life,[19] are all essential to understanding and appreciating the gravity of the issues presented in this Petition.

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[12] Opposition, p. 12.

[13] All references to "Rules" mean Rules of the Supreme Court of the United States.

[14] Appendix B-357.

[15] Appendix B-370.

[16] Appendix B-372, B-373

[17] Appendix B-369, B-370.

[18] Appendix B-359 - B-363.

[19] Petition, p. 13; Appendix B-394.

III. Respondent Researcher, Charles Swerdlow, M.D., now admits to this Court that he experimented on patients without their knowledge or consent. But, to the California Supreme Court he claimed there was no experimentation.

In his answer to the Petition for Review to the California Supreme Court, Dr. Swerdlow stated,[20] "this is not an action concerning human experimentation." Now he makes no such claim. Instead, he admits that medical experimentation is the focus of the Complaint in this case.[21]

Dr. Swerdlow also admits that he subjected patients to a study of the effectiveness of the temperature probe at issue in this cause.[22]

He then attempts to distinguish patients who were included in the surreptitious study from those who were not. In particular Dr. Swerdlow claims that the study was directed only to the first 12 patients in the experimental series, while those that followed were somehow "left out." Conspicuously missing from Dr. Swerdlow's depiction is any indication of an investigative plan, informed consents from the study participants, a showing of UCLA IRB approval for this study and ,an IDE from the FDA. But, in reality this

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[20] Answer to Petition for Review to the California Supreme Court, at p. 1.

[21] Opposition, p. 2.

[22] Opposition, p. 5: "The study established that ..."

lack of candor is simply an admission that the study was not conducted according to the federal regulatory requirements -- just as was alleged in the Complaint.

The Respondent Researchers in this case simply falsified their experimental results by "limiting the data points" to only those patients who suffered no ill effects.[23] But, falsification of data and documents appears to be a much too common practice at the University of California, as this petition has illustrated.[24]

After Nadine's death on 12 September 2004, and certainly by the time Dr. Swerdlow gave his presentation to the 2005 ACC Scientific Session, in March 2005, he knew that a device whose purpose was to monitor core body temperature during surgery[25], would not function as an "atrio-esophageal fistula monitor. Proof that this device could not perform as envisioned was subsequently achieved in a laboratory study, which was presented to the California Court of Appeals in this Petitioner-Appellant's Reply brief.[26]

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[23] See Petition Appendix B-99 - B-101: Publication of "Less Than Entirely True" Research Results

[24] Generally, Petition, pp. 13-22; Appendix B-287, B-288 - B-314.

[25] Core temperature, also called core body temperature is the temperature of structures deep within the body, as opposed to peripheral temperature such as that of the skin. (http://medical-dictionary.thefreedictionary.com/core+temperature).

[26] Petition Appendix B-405 - B-407.

IV. After admitting to covert experimentation on unsuspecting patients, Respondent Charles Swerdlow, M.D., cannot now claim that his conduct was "within the standard of care" or claim that he was entitled to the summary judgment at issue in this petition.

Dr. Swedlow has virtually conceded, *supra*, that (1) the issues in this case regard medical experimentation and (2) that he subjected patients to a surreptitious medical device study.

That said, Respondent Researchers in this case could not obtain summary judgment based on expert declarations that their conduct was within the standard of care, because medical and human subject research "is not standard; it is speculation, approximation, and inquiry."[27] (*Spenceley v. M.D.Anderson Cancer Ctr.*, 938 F. Supp. 398, 398 (S.D. Tex.1996)

With this in mind, an examination of the California Court of Appeals Opinion in this case shows it to be self-contradictory on the issue of expert opinion. On Petition, Volume I, Appendix page A-42, the Opinion states:

> "an expert's opinion rendered without a reasoned explanation of why the underlying facts lead to the ultimate conclusion has no evidentiary value because an expert opinion is

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[27] Petition, pp. 24-27; Appendix B-359: The failed temperature probe study was based on supposition and speculation -- not science; Appendix B-329 - B-335: Medical Research or Medical practice?

> worthno more than the reasons and facts on which it is based." *(Bushling v. Fremont Medical Center* (2004) 117Cal.App.4th 493, 510 (Bushling).[28]

But, when discussing the Respondent Researchers use of the Vital probe at issue in this case, no such requirement was made of Respondents' experts,[29] -- who never even addressed the issues framed by the complaint much less provided any line of facts-to-conclusions reasoning.[30]

Put another way, if the use of an anesthesiologist's temperature probe in the manner complained of was announced to the medical community as "experimental" and "research" in March, 2005,[31] then it was not "standard" in August, 2004, when the events which gave rise to this litigation occurred.

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[28] Appendix A-42, Opinion, p. 9.

[29] Appendix A-60, Opinion p. 22.

[30] See Appendix C-21: AOB Excerpt re: Proof of Medical Experimentation

[31] Petition Appendix B-247: Conti, Jamie, M.D., Annual Session Highlights, June7, 2005, J Am Coll Cardiol 2005; Vol. 45, No. 11,Suppl B, ACC 2005: 30B–2B; Appendix B-243: Cesario D, Snivkumar K, Valderrabano M, Wiener I, Swerdlow C., Esophageal temperaturemonitoring during left atrial catheter ablation foratrial fibrillation. J Am Coll Cardiol 2005;45 SupplA:114A

V. Dr. Swedlow claims that the issues in this Petition do not apply to him. However, even though he is apparently a "part-time" public employee, the issues apply to his conduct, in any event.

At the time of Nadine's procedure, Dr, Swerdow was a Professor of Clinical Medicine at UCLA, complete with UCLA email account.[32] Dr. Swerdlow's current biographical page describes him thus:

> Clinical Professor of Medicine,
> David Geffen School of Medicine, UCLA
> Electrophysiology and Pacemakers [33]

Dr. Swerdlow was, at the time of the events which gave rise to this cause, and/or is, indisputably an employee of a state entity -- the University of California.

But, under the facts of this case he is still a "state actor," because he acted in concert with state actors using state property at a state facility.[34]

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[32] Petition Appendix B-223: Dr. Swerdlow identifies himself as a "Clinical Professor of Medicine UCLA" and at Appendix B-221: is found his email address: "Chuck Swerdlow <swerdlow@ucla.edu>"

[33] http://www.cvmg.com/Physicians.aspx?ID=15

[34] The University of California is a separate branch of California Government: California Constitution, art. IX, § 9(a).

This Court has held: private parties are state actors when they are "willful participant[s] in joint action with the State or its agents." (*Dennis v. Sparks*, 449 U.S. 24, 27 (1980))

Lastly, the federal regulations regarding medical device experimentation apply to everyone, whether or not they are state actors, even to "part time professor," Respondent Researcher, Charles Swerdlow, M.D.[35]

Dr. Swerdlow's assertion that the issues in this Petition do not apply to him is without merit.

VI. Contrary to Dr. Swerdlow's contention, Rule 10 provides that conscription by government and/or its agents, of unknowing and helpless patients as objects of medical experimentation and student training, is one of the most compelling reasons of all for this Court to grant certiorari.

In his opposition, at page 1, respondent Charles Swerdlow, M.D., claims that there is no compelling reason, under Rule 10 or granting certiorari in this case. The assertion is without merit. Rule 10 provides that its provisions are " neither controlling nor fully measuring the Court's discretion." In particular, Rule 10 (c) provides that this court may intervene when:

> a state court or a United States court of appeals has decided an important question of

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[35] Petition Appendix B-288 - B-302: "FDA regulations apply to 'everyone.'")

> federal law that has not been, but should be, settled by this Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court.

It should be elementary that "[i]t is the duty of courts to be watchful for the constitutional rights of the citizen, and against any stealthy encroachments thereon. Their motto should be *obsta principiis*." (*Boyd v. United States*, 116 U.S. 616, 635 (1886)). "The right to be free of state-sponsored invasion of a person's bodily integrity is protected by the [constitutional] guarantee of due process."*In Re Cincinatti Radiation Litigation*, 874 F. Supp. 796, 810-11 (S.D. Ohio 1995).

That said, there is more than enough justification for this court to review the alleged constitutional deprivations claimed in this cause.

VII. Respondent Charles Swerdlow, M.D., asserts that Nadine did not restrict her consent to specifically identified surgeons. But, this claim is shown to be entirely false by the documents now before this court.

Dr. Sweredlow looks to repudiate his duty to care for Nadine's health by baldly claiming that Nadine did not specifically identify the physicians who would perform her surgery.[36] However, the "UCLA Medical Center Consent to Operation and Other Procedures"

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[36] Opposition, p. 6.

form Nadine filled with Respondent Kalyanam Shivkumar, M.D. and reproduced at Appendix C-17, shows this statement to be false. At Nadine's insistence, Dr. Shivkumar wrote-in both his and Dr. Swedlow's names as operating surgeons. The handwriting on the reproduced form is Dr. Shivkumar's (scanned from the record and inserted in their proper positions). Note that it was Dr. Swerdlow who introduced this record into evidence, so he cannot now deny that Nadine did not make a choice as to specific surgeons. This form taken together with Nadine's email communication with Dr. Swerdlow[37] and Valer's declaration,[38] demonstrate that Nadine did everything any reasonable and prudent patient could to secure the personal performance Drs. Swerdlow and Shivkumar promised her.[39] Consequently, there was no consent to anyone's performing Nadine's procedure, but Drs. Swerdlow and Shivkumar.

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[37] Petition Appendix B-227: 1 December 2003 email between Dr. Swerdlow and Nadine re: choice of surgical team

[38] Petition Appendix B-202 - B-203, B-207: Declaration of Plaintiff Valer V. Secarea, Jr. in opposition to Summary Judgments

[39] Petition Appendix B-70: Drs. Swerdlow and Shivkumar Agree to Perform Nadine's Ablation

VIII. Researcher Charles Swerdlow, M.D. asks this Court to deny this Petition on the basis of a lack of conflict in the courts, all the while patients continue to be "kidnaped" from their hospital beds and subjected to covert medical experiments.

Dr. Swerdlow complains there is no "split in authority" for this court to decide.[40] A "disagreement among courts" is a thin reed upon which to rest the lives of helpless and unsuspecting patients subjected to covert medical experiments, while they await some disparity among court rulings to trigger a review of their rights under the U. S. Constitution. [41]

However, to satisfy Dr. Swerdlow's objection, it should be noted that in California the First and Fourth Appellate districts, respectively, have rendered diametrically opposed opinions on the subject matter of this cause. In *Daum v. Spine Care Medical Group, Inc.*, 52 Cal.App.4th 1285, 1305 [61 Cal.Rptr.2d 260](1997),[42] the court held that:

> [T]he Legislature and the FDA, in their wisdom, have decreed that patients participating in clinical trials of

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[40] Charles Swerdlow, M.D., Opposition to Petition for Writ of Certiorari, p. 3 (hereinafter, "Opposition").

[41] Petition, pp. 13-22: "This Case Involves Nation-wide Matters of Life and Death."

[42] Petition Appendix B-288.

> investigational devices must be informed in writing, with a copy for themselves, of the nature of the trial and the device. Neither physicians nor courts are free to disregard these requirements.

But, the Court of Appeal in this case characterized these same disclosure requirements as unspecified statutes and regulations.[43] This Petitioner suggests that this is a "disparity" worthy of this Court's attention.

IX. Respondent Charles Swerdlow, M.D. claims that the loss of life to medical experimentation underlying this Petition is unlikely to recur, even though many continue to be subjected to covert experimentation.

Contrary to Dr. Swedlow's contention, the on-line FDA "Inspections, Compliance, Enforcement, and Criminal Investigations" home page[44] and the on-line U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) warning letters home page[45] reveal that surreptitious human subject experimentation on

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[43] Petition, p. 7, footnote 21; Appendix B-38 - B-39: "Use of the New Device Required NADINE'S Informed Consent."

[44] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

[45] http://www.hhs.gov/ohrp/compliance/letters/index.html

helpless and unsuspecting patients has been and is an ongoing and recurring issue. Consequently, the cause underlying this Petition is not uniquely fact-bound, but is one example of a ontinuing nation-wide litany of patient mistreatment at the hands of human subject researchers.

X. **Conclusion: The only question posed by Researcher Charles Swerdlow's objections to this Petition is: how many more helpless and unsuspecting patients will die before this Court determines whether there is constitutional protection from this conduct?**

This Petitioner asserts that the result in this case does not begin to comport with the most basic notions of justice and morality. And, it is for that reason, and those appearing in the Petition, that this Court should grant review -- for the sake of all Americans, both now and into the future.

Dated: 24 September 2009

Respectfully submitted,

Valer V. Secarea, Jr.
Petitioner, Appellant and Plaintiff
In Propria Persona

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APPENDIX C

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California Evidence Code
§§ 451, 452, 453, 454, 455, 459
(Judicial Notice)

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California Evidence Code § 451

Judicial notice shall be taken of the following:

(a) The decisional, constitutional, and public statutory law of this state and of the United States and the provisions of any charter described in Section 3, 4, or 5 of Article XI of the California Constitution.

(b) Any matter made a subject of judicial notice by Section 11343.6, 11344.6, or 18576 of the Government Code or by Section 1507 of Title 44 of the United States Code.

(c) Rules of professional conduct for members of the bar adopted pursuant to Section 6076 of the Business and Professions Code and rules of practice and procedure for the courts of this state adopted by the Judicial Council.

(d) Rules of pleading, practice, and procedure prescribed by the United States Supreme Court, such as the Rules of the United States Supreme Court, the Federal Rules of Civil Procedure, the Federal Rules of Criminal Procedure, the Admiralty Rules, the Rules of the Court of Claims, the Rules of the Customs Court, and the General Orders and Forms in Bankruptcy.

(e) The true signification of all English words and phrases and of all legal expressions.

(f) Facts and propositions of generalized knowledge that are so universally known that they cannot reasonably be

the subject of dispute.

California Evidence Code § 452

Judicial notice may be taken of the following matters to the extent that they are not embraced within Section 451:

(a) The decisional, constitutional, and statutory law of any state of the United States and the resolutions and private acts of the Congress of the United States and of the Legislature of this state.

(b) Regulations and legislative enactments issued by or under the authority of the United States or any public entity in the United States.

(c) Official acts of the legislative, executive, and judicial departments of the United States and of any state of the United States.

(d) Records of (1) any court of this state or (2) any court of record of the United States or of any state of the United States.

(e) Rules of court of (1) any court of this state or (2) any court of record of the United States or of any state of the United States.

(f) The law of an organization of nations and of foreign nations and public entities in foreign nations.

(g) Facts and propositions that are of such common knowledge within the territorial jurisdiction of the court that they cannot reasonably be the subject of dispute.

(h) Facts and propositions that are not reasonably subject to dispute and are capable of immediate and accurate determination by resort to sources of reasonably indisputable accuracy.

California Evidence Code § 453

The trial court shall take judicial notice of any matter specified in Section 452 if a party requests it and:

(a) Gives each adverse party sufficient notice of the request, through the pleadings or otherwise, to enable such adverse party to prepare to meet the request; and

(b) Furnishes the court with sufficient information to enable it to take judicial notice of the matter.

California Evidence Code § 454

(a)In determining the propriety of taking judicial notice of a matter, or the tenor thereof:

(1) Any source of pertinent information, including the advice of persons learned in the subject matter, may be consulted or used, whether or not furnished by a party.

(2) Exclusionary rules of evidence do not apply except for Section 352 and the rules of privilege.

(b) Where the subject of judicial notice is the law of an organization of nations, a foreign nation, or a public entity in a foreign nation and the court resorts to the advice of persons learned in the subject matter, such advice, if not received in open court, shall be in writing.

California Evidence Code § 455

With respect to any matter specified in Section 452 or in subdivision (f) of Section 451 that is of substantial consequence to the determination of the action:

(a)If the trial court has been requested to take or has taken or proposes to take judicial notice of such matter, the court shall afford each party reasonable opportunity, before the jury is instructed or before the cause is submitted for decision by the court, to present to the court information relevant to (1) the propriety of taking judicial notice of the matter and (2) the tenor of the matter to be noticed.

(b)If the trial court resorts to any source of information not received in open court, including the advice of persons learned in the subject matter, such information and its source shall be made a part of the record in the action and the court shall afford each party reasonable opportunity to meet such information before judicial notice of the matter may be taken.

California Evidence Code § 459

(a) The reviewing court shall take judicial notice of (1) each matter properly noticed by the trial court and (2) each matter that the trial court was required to notice under Section 451 or 453. The reviewing court may take judicial notice of any matter specified in Section 452. The reviewing court may take judicial notice of a matter in a tenor different from that noticed by the trial court.

(b) In determining the propriety of taking judicial notice of a matter, or the tenor thereof, the reviewing court has the same power as the trial court under Section 454.

(c) When taking judicial notice under this section of a matter specified in Section 452 or in subdivision (f) of Section 451 that is of substantial consequence to the determination of the action, the reviewing court shall comply with the provisions of subdivision (a) of Section 455 if the matter was not theretofore judicially noticed in the action.

(d) In determining the propriety of taking judicial notice of a matter specified in Section 452 or in subdivision (f) of Section 451 that is of substantial consequence to the determination of the action, or the tenor thereof, if the reviewing court resorts to any source of information not received in open court or not included in the record of the action, including the advice of persons learned in the subject matter, the reviewing court shall afford each party reasonable opportunity to meet such information before judicial notice of the matter may be taken.

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California Rules of Court Rule 8.252:
(a) Judicial Notice
(b) Findings on Appeal
(c) Evidence on Appeal

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Rule 8.252 (a). Judicial notice on appeal.

(a) Judicial notice

(1) To obtain judicial notice by a reviewing court under Evidence Code section 459, a party must serve and file a separate motion with a proposed order.

(2) If the matter to be noticed is not in the record, the party must serve and file a copy with the motion or explain why it is not practicable to do so.

(b) Findings on appeal

A party may move that the reviewing court make findings under Code of Civil Procedure section 909. The motion must include proposed findings.

(c) Evidence on appeal

(1) A party may move that the reviewing court take evidence.
(2) An order granting the motion must:

(A) State the issues on which evidence will be taken;
(B) Specify whether the court, a justice, or a special master or referee will take the evidence; and
(C) Give notice of the time and place for taking the

evidence.

(3) For documentary evidence, a party may offer the original, a certified copy, or a photocopy. The court may admit the document in evidence without a hearing.

UCLA MEDICAL CENTER
CONSENT TO OPERATION
AND OTHER PROCEDURES

(Reproduced as well as could be, including scanned original handwriting of respondent Kalyanam Shivkumar, M.D.. Naming himself and respondent Charles Swerdlow, M.D., as Nadine's surgeons)

Note that the court record does not contain the referred to anesthesia options on the back of the form.

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[Original: Page 1; 4.CT.892]

UCLA Medical Center
CONSENT TO OPERATION
AND OTHER PROCEDURES

SECTION I. Patient Information

1. I hereby authorize and direct

Shivkumar, Swaroop. M.D., and/or associates and assistants of his/her choice to perform the following operation(s) or procedure(s):

electrophysiology study; radiofrequency ablation of atrial fibrillation
Name of operation or procedure
transesophageal echocardiogram; cardiac catheterization

2. I hereby authorize and direct the above named surgeon or other physician and/or associates and assistants to provide or arrange for the provision of such additional services or related procedures that are deemed necessary or advisable. including, but not limited to, pathology and radiology services.'

3. All operations and procedures may involve risks of unsuccessful results, complications, injury, or even death, from known and unforeseen causes. You have the right to be informed of such risks, as well as the nature of the operation or procedure, the expected benefits or effects of such operation or procedure, and the available alternative methods of treatment and their risks and

benefits. You also have the right to be informed as to whether your physician has any independent medical research or economic interests related to the performance of the proposed operation or procedure. Except in cases of emergency, you have the right to receive this information and to give your consent before operations or procedures are performed. You have the right to consent to or to refuse any proposed operation or procedure at any time prior to its performance. No warranty or guarantee is made as to the result or cure.

4. Your signature below confirms that you authorize the pathologist to use his or her discretion in the disposition or use of any member, organ, or other tissue removed from your person during the operation or procedure identified above.

Your signature on this form indicates that: (1) you have read and understood the information contained herein; (2) you have been verbally informed about this operation or procedure; (3) you have had the opportunity to ask questions regarding this operation or procedure; (4) you have received all of the information you desire; and (5) you authorize add consent to the performance of the operation or procedure.

/s Nadine Secarea/	/s K. Shivkumar & witness/
Signature of patient, conservator or guardian	Signature of witness

(Blank)	8/10/2004	(Blank)
If signed by other than the patient, indicate relationship	Date	Time

Your signature below indicates that: (1) you have discussed the risks, benefits, and options of anesthesia (as listed on back of form) with a representative of the anesthesia department; (2) you have received answers to all of your questions; and (3) you authorize and consent to the anesthesia plan discussed.

/s Nadine Secarea/	/s witness/	8/11/04
Signature	Signature of witness	Date

SECTION II. Patient Declines to be Informed

Although I have been given an opportunity to be advised as to the nature and purpose of the operation or procedure, and the risks, benefits, and alternatives. I specifically decline to be so advised, but I do give my consent to the operation. No warranty or guarantee has been made as to the result or cure.

(Blank)	(Blank)	(Blank)
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AOB Excerpt re:
Proof of Medical Experimentation

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[AOB Original, Page 57]

2. UCLA Defendants' Motion for Summary Judgment did not meet the initial burden of proof that all theories of liability raised had no merit and that there were no triable issues

[AOB Original, Page 62]

d. There is a triable issue as to whether the UCLA Respondents conducted medical experimentation upon Nadine, which required her informed consent

Secarea alleged respondents Drs. Swerdlow, Cesario, and Shivkumar, and the Regents conducted medical experiments on Nadine without her informed consent and in violation of human experimentation regulations. (II.O:AOB:7; VII.B.1.m:AOB:33)

Respondents Regents, Drs. Shivkumar and Cesario filed their motions for summary judgment, claiming they did not conduct medical experimentation. (2.CT.554) They relied on Dr. Natale's expert testimony. (2.CT.564:8-21) Dr. Swerdlow also challenged this allegation in his motion, relying on the Declaration of Dr. Packer, who without reasons or explanation simply stated, "The use of an esophageal temperature probe was reasonable and within the standard of care." (3.CT.688:9-10, 771) An expert's opinion must be supported by reasons and explanations. (*Kelley v. Trunk* (1998) 66 Cal. App.4th 519, 524.) But, these experts' conclusory statements are not.

However, both experts miss the issue framed by the Second Amended Complaint which is whether the Vital Temp model 1101-18Fr Series 400 Esophageal Stethoscope, manufactured by Vital Signs, Inc. can do the job of an atrio-esophageal fistula prevention monitor. (II.O:AOB:7; 1.CT.122:11-124:18; V.C.2:AOB:23)

[AOB Original, Page 63]

It is not the probe itself, but its novel application and the reliance placed on it's performance in that role during Nadine's surgery that is in issue. (1.CT.119:11-121:4; [SAC §§178-184]; V.C.2:AOB:23).

Neither Defense expert, Dr. Packer nor Dr. Natale, addressed that question. And, neither Dr. Natale nor Dr. Packer claimed the required knowledge or expertise in temperature measurement nor knowledge of the principles of operation of the Vital Temp probe, to opine on this issue, as it is framed by the Second Amended Complaint (V.C.3:AOB:23)

However, Dr. Natale came closest to answering the question. He stated that "[t]here is no standard approach to avoiding an atrio-esophageal fistula." Dr. Swerdlow made a similar statement in an e-mail to Valer. (1.CT.120:12-18; 4.CT.912; 3.CT.804:24-26) It can be inferred from these statements that any application of a temperature probe to act as an atrio-esophageal fistula monitor is, *ipso facto*, not only experimental, but speculative as well.

Secarea provided literature from the 54th Annual Scientific Session of the American College of

Cardiology (4.CT.898-904; 3.CT.789-790, 820-822, 1097, 1100-1101), at which time Drs. Swerdlow, Shivkumar, and Cesario presented their findings on the use of a temperature probe in cardiac catheter ablations as performed on 13 patients. (4.CT.899, 903-904; Exhibits 7 and 8) If the use of the temperature probe was "standard," as respondents' experts assert, then such presentation would be of little

[AOB Original, Page 64]

interest. Put another way, if the use of an anesthesiologist's temperature probe in the manner complained of was announced to the medical community as "experimental" in March, 2005, then it was not "standard" in August, 2004.

This evidence raises a triable issue, or at a minimum, a strong inference as to whether respondents were conducting medical experiments on Nadine. Respondents did not present any evidence the appropriate consents – or even FDA approval – had been obtained. In addition, their research interests should also have been disclosed. (IV.B.1.i:AOB:30) As a result, the lower court erred in granting summary judgment.

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